24 Introduction to Computers in Monitoring

Terry P. Clemmer and Reed M. Gardner

Medical informatics encompasses the broad range of issues in the management and use of biomedical information. It includes medical computing but also incorporates a knowledge of the synthesis, nature, and use of medical information itself. For the science of medical informatics to be successful in achieving the primary goal of improving health care, it requires that the combined skills and knowledge of computer scientists, clinicians, nurses, paramedical professionals, and researchers be brought together in a harmonious collaborative effort.

Research efforts to develop more sophisticated hardware and software without bedside testing and integration into the clinical environment will rarely achieve the goal of becoming a practical and useful system that enhances patient care. That is not to say that more basic research-oriented programs such as physiologic or pharmacologic modeling created outside the clinical environment are not useful, but to influence care they must eventually be brought to the bedside. The situation demands that there be a close collaborative relationship between the scientists in medical informatics and the clinician, and that they work together routinely on both research and clinical projects with the specific goal of improving patient care.

The intent and purpose of medical informatics are to strengthen and improve medical decision making and patient care; thus the structure and design of the system should promote this goal above all others. An integrated medical information system brings with it many advantages in meeting the goal of improving health care.[1,2] It makes possible the retrieval of all the patient's information at a single location for review by the clinician, thus saving time and enhancing the utilization of the system rather than making data retrieval repetitious, slow, and burdensome. Using standardized menu formatting throughout the hospital simplifies this process by allowing personnel in all areas and locations to access data in the same way. By having the data integrated, reports and displays can be created to bolster the transfer of information to the health-care provider in such a manner as to focus attention on specific problems, thus strengthening medical decision making by ensuring that the data are complete, appropriately integrated, and properly presented.[3-6]

In addition, an integrated database allows development of more sophisticated data-driven alerting,[7-11] quality assurance,[12-16] and decision-making programs that reduce errors, improve care, and increase reliance on the system. Databases also facilitate research, enhance administrative uses, and allow some tasks to be accomplished that would be difficult or impossible otherwise.[17]

However, an integrated patient data management system also presents many challenges to the developers. Indeed, these challenges are the gene-

sis of the field of medical informatics. Among these challenges are (1) acquisition of data, (2) data quality control, (3) management of a large quantity of data in a functional way, (4) standardization and transfer of data, (5) making the data useful to the clinician, (6) learning how to use the data in the continuous quality improvement (CQI) process, (7) making the data useful to the researcher, and (8) logistical, cost, and confidentiality issues. These challenges are addressed separately and in some detail in this chapter. Many of these problems have not been resolved, and they present fertile areas for future medical informatics research.

TECHNIQUES FOR REDUCING DATA ENTRY TIME AND EFFORT

For a computer system to be usable, the cost and effort of data input must be minimized. Several techniques are used to facilitate data entry. As a first step, the direct interface of devices capable of generating digital signals is desirable. Many devices are readily adaptable to this concept, and direct interface between bedside monitors and other hospital computers such as those in the clinical laboratory are now routine. Bar-coding input of patient identification, medications, and supplies could simplify or semiautomate data entry. Other devices have output processes that can be directly interfaced with some effort.[18-21] These include intravenous infusion devices, pulse oximeters, venous oximeters, ventilators, and gastric pH monitors.

Data derived from direct input are not achieved without difficulties, however. First, it must be made certain that the device can be identified with the correct patient from whom data are being collected or to whom the therapy is being delivered. Improper patient identification is still a major concern for every hospital. Automated data entry has its own form of identification errors that one must strive to prevent. These problems generally revolve around the human error of failing to "tell" the computer to which patient the devices are connected. When patients are disconnected and reconnected to as many as 15 different devices when they are moved for special procedures or transferred to other nursing units, the potential for error is large. Second, although the direct input of data eliminates many data entry errors, the quality of automated data is not guaranteed.[19,20] A directly measured blood pressure obtained from a transducer may have erroneous signals for mechanical reasons—because of interferences such as occurs during blood drawing or line flushing, or because of sampling "nonrepresentative" physiologic data while the patient is being stressed, placed in a different position, or is in the process of responding transiently to a medication or procedure. Techniques to control data quality will be addressed in the following section. Third, the interface problems can be very challenging at times. The linking of different types of computers or medical devices is not simple. Because of lack of standardization, the interface problems of each computer, instrument, or device may have to be resolved individually.

The need to develop computer and device communications standards is clear. The Institute of Electrical and Electronic Engineers (IEEE) is pursuing this area so that in the future most devices will be compatible with a common "medical information bus" (MIB) that will allow the computer to access the information from many different types of instruments and to communicate back to these devices.[6,19-23] Such communication will allow the health-care provider to know what the computer perceives it is monitoring or controlling. For example, the computer, as perceived from its database, can indicate on the LED (light-emitting diode) display of the infusion pump the drug being infused, thus permitting the caregiver to confirm proper communication with the computer. Such two-way communication also helps with patient identification, and in the future it will be essential for closed-loop control of devices. In addition, standardization of device interfaces enhances the likelihood of obtaining timely and accurate data and reduces the possibility of technical and systems errors.

Another problem with direct device interfacing is maintaining data capture while moving patients. While the patient is located in one place, the patient identification problems are reduced and hardwired computer connection is possible. But during patient transport and during lengthy patient procedures in the operating or radiology suites, continuous monitoring and reliable data capture may be compromised. This presents new challenges that are met by either portable storage of information for later retrieval or telemetry of data. Alternatively, the ability to change the patient's location quickly and while maintaining both proper patient identification and as little interruption of data storage as possible should be ensured. The availability of new portable monitors, which store data and can later dump the data into the integrated system, is one approach to the dilemma. Another option is providing a computer interface in all operating and special procedure areas, as well as software that will allow easy transfer of patient location.

A considerable amount of data cannot be di-

rectly obtained from bedside devices. This includes information such as bolus medications, oral medications, nursing tasks, and most physical findings. If data are entered into the computer in "free-text" form, it is difficult to use the data for computerized alerting, quality assurance, decision-making support, and research purposes; data entered in free-text form carry with them as well the problems of typographic and spelling errors. When possible, structured, menu-driven data entry is desirable because it is faster and uniform. This can be accomplished in several ways. The mouse, track-ball, light-pen, and touch-screen are popular methods that use a point-and-click system. Many systems using these devices are now available.[24] For speed, however, the 10-key pad is hard to beat once the operator becomes familiar with the keyboard system and the menus.[17] Using the keyboard allows the user to "stack" commands and drop quickly to the desired menu and location for charting. With the point-and-click systems, the user must wait for the screen to appear before it is possible to point again; this feature may slow the process while still demanding the use of the numerical keys to chart much of the numerical data.

Regardless of which charting method is selected, access to a computer terminal is of utmost importance in providing a friendly, usable system. In the intensive care unit (ICU) it is desirable to have a terminal at each bedside, along with a stool or chair for comfort so that clinical personnel can chart directly into the computer. Direct computer entry eliminates the need to write out the information in longhand or to chart from memory. A bedside terminal guarantees the availability of a computer and allows the personnel to stay in the room, thus saving time and effort. In addition to the bedside terminals, other terminals at the nurses station are convenient for charting when the patient is resting, for review of data by the physician and others, and for administrative purposes such as ordering supplies. When data are recorded in a delayed fashion the accuracy and timing have been shown to cause frequent errors.[19] The advantages of real-time charting are accentuated when one is trying to drive therapy with computerized protocols that contain time-driven decisions. If data are late or are unavailable to the computer, decisions, based on data entered earlier, either will not be made or will be made incorrectly. This is a problem area in which direct data acquisition from devices can be very valuable. At the critical time of clinical decision making, accurately and efficiently charted data are available to the physician instead of being stored in the nurse's mind or pocket. With an integrated system, information can also be accessed from other areas of the hospital and from medical clinics, physicians' offices, or even homes.

TECHNIQUES FOR CONTROLLING QUALITY OF DATA ENTERED

One of the most important problems in medical informatics is the entry of accurate data. Inaccurate data can result in compromises to patient care and loss of the care team's confidence in the system, and even the team's refusal to use the system. In addition, poor-quality data severely limit the ability to use the power of the information system because alerts, quality assurance programs, and clinical decision making cannot be effective if treatment recommendations are generated from fallacious data. Therefore it is crucial to develop methods to enhance the quality and consistency of patient data entry.

The best control over the quality of the data is to *constantly use the data.* The more the data are used by the health-care team, the greater the likelihood errors will be found. Those who know the patient best are most likely to recognize errors when they are using the data to make decisions.[25] The care teams are also the most critical of inaccuracies because their actions are determined by decisions made from the data and because they are legally and ethically liable for these actions. Therefore, they are demanding of the quality of the data and will insist on accuracy. It is desirable that everyone concerned with the care of the patient use the computer system properly and not just blindly enter or accept data.

If errors are identified, then it is imperative that a simple mechanism to correct the errors be available. Otherwise, even though the error is recognized and the correct information is used, the patient's record may not be corrected. Incorrect information will interfere with other valuable functions of the data, such as in the alerting system and in quality control, decision-making protocols, and research. The key then is to *use the data* and to *correct them* when errors are found.

Another method of improving the quality of data is to create "smart filters" that will not allow the entry of data that are outside of credible limits. Certainly for physiologic data there are values that are impossible, and keystroke errors resulting in such values should be rejected. Other data outside reasonable limits should require verification before being logged, to reduce entry mistakes.

When there is redundancy in the monitored data, they can be cross-checked to establish correctness. An example would be the heart rate from the electrocardiogram (ECG), the pulse rate from an arterial blood pressure monitor, and the pulse

rate from a pulse oximeter.[19,20] Thus ECG artifact resulting in a rate significantly different from the other pulse monitors could be questioned. Other examples might include hemoglobin values from a blood gas compared with those from a complete blood count (CBC), the pH verification with the electrolyte panel, weights correlated with intake and output record, respirations from the bedside monitor with data from the ventilator, the arterial partial pressure of oxygen (Pao_2) with the fraction of inspired oxygen, and the Glasgow Coma Score with sedative and paralytic medications.

Because hand entry of data is associated with many entry errors,[19,20] automatic data entry is desirable but introduces problems of its own. One of the problems is that under normal conditions health-care providers unconsciously filter data, recording only what they perceive as being representative of the patient's condition. For example, if a patient is being turned or is on the bedpan, the transient rise in blood pressure will not be recorded; the staff will wait until the stress is over and the patient returns to baseline status before inputting vital signs. When a patient is coughing or bucking a ventilator, the caregiver will not report the peak airway pressure but will wait until the patient has passed this episode. With time-driven automatic data sampling, waiting may not be possible and data may thus be stored that would not be useful for decision making, quality assurance, or research. On the other hand, the nurse's perceptions of representative data have been frequently shown to be wrong and can themselves become a source of erroneous data.[16] One method to avoid both of these problems is to have the automated data verified or edited by the nurse or therapist. Another is to have the caregiver tell the computer when to sample and when to consider these data different from routine sampling and of higher value for storage and decision-making purposes. This could be simplified to a few keystrokes on the keyboard to signal the computer to sample the output from all the devices connected to the patient simultaneously at the time the provider determined these data to be representative of the patient's condition. Other mathematical filtering or averaging of data might be appropriate in some circumstances to eliminate transient fluctuations, but caution should be applied so as not to miss clinically relevant data. A methodology of sampling blood pressure, heart rate, and pulse oximetry has been developed with the use of 30-second sampling and subsequent selection of 5- or 15-minute medians for reporting, which eliminates very transient changes but will include larger or more sustained changes.[83] This methodology has been shown to be more representative of the patient's status and to eliminate many spurious values from the medical record.

Another technique for controlling data quality is to generate reports that become the legal medical record and to have them reviewed by the caregiver for accuracy verification.[26] Other reports routinely given to personnel responsible for statistical analysis and quality assurance simplify the recognition of errors and problem areas in data quality. Once again, the idea of *using the computer data frequently* is the key to acquiring quality data.

MANAGING AND STORING DATA

The quantity of data available on any one patient in the ICU is phenomenal. With the ability to sample data automatically, it is possible to gather thousands of data points each day for each monitored parameter and each of the support devices. This presents the clinical and medical informatics team with the enormous challenge of determining which data are needed, how often it is necessary to sample, and which data to store.[27] If data are redundant, do we need to store the output from all the devices? If so, do we use the same codes for redundant data? If the redundant data are not identical, which data point takes priority? If there are redundant data, which should be used for decision making, quality assurance, and alerts? These questions provide fertile areas for research activities and are crucial to systems development. Currently, these decisions are arbitrarily made with little or no scientific validation.

Some modeling can be used to help make such decisions. The rate of change of any given parameter determines how often the signal must be sampled to detect significant change.[27] For example, the serum albumin changes very slowly, over hours or days, so sampling it every few minutes would be inappropriate. The heart rate, however, may change in seconds, so if all changes are to be detected, continuous beat-to-beat monitoring is necessary. We may want to monitor heart rate continuously and have an alarm activated if certain limits are exceeded, but do we need to store all the data? Most manual and current computer systems store data at fixed time intervals. For example, they are measured and logged every 2 hours. Perhaps it would be better to store data when "changes" are detected. This brings us back to transient changes caused by such factors as patient movement and medications. Therefore, perhaps it would be best to require that the change be more than transient, but then we have to define what "transient" means. These are areas in which more knowledge and research are needed.

Another challenge is to discover which data are actually used by the care team in making deci-

sions.[28] We generate enormous volumes of data, but data used in the decision-making process and prognosis often represent only a few items.[29] An example is the measurement of respiratory data that can inlcude tidal volume, ventilatory rate, blood gases, thoracic compliance, three different airway pressures, airway resistance, pressure volume curves, vital capacity, forced vital capacity, lung volumes, inspired oxygen concentration, and the chest x-ray examination.[19-21,30,31] Are all these data required to make decisions about the ventilator? What is really relevant and needed? How are decisions really made? Recent experience leads us to believe that only a few data items are actually being used in the process of most clinical decision making.[30,31]

Even if all of these data are needed for immediate decision making, do we need to store them all on a long-term basis? Can we eliminate redundant data in long-term storage? What kinds of questions are asked when long-term data storage is used for analysis? Our experience is that long-term data storage is very useful in answering questions that arise in computer systems design. An example is the use of long-term storage data to develop a consultative blood-ordering system to replace our critiquing system.[32] With today's rapid expansion of inexpensive data storage, perhaps we can afford to keep them all. But when it comes to analyzing data, the sheer volume may a hindrance. Another question is, how long should long-term data be stored? Is immediate access required? How long is long-term (months, decades), and how immediate is immediate (seconds, minutes, hours)? These are all questions needing consideration and answers as informatics systems are planned and implemented.

STANDARDIZATION AND TRANSFER OF DATA

For computer-stored data to be useful, they must be searchable and retrievable. Therefore, it is critical that the data be in a standard format and coded in such a way that they can be easily identified, searched, retrieved, and used by various users for multiple purposes. Thus blood oxygen tension may be entered and used by laboratory technicians, nurses, physicians, respiratory therapists, and researchers. It must be coded and entered in such a way that it can be used by everyone.[33,34] In institutions with many departments, divisions, and people, each with specific interests and ability to write particular programs, the danger of confusion, inappropriate duplication, and lack of coordination of data coding and storage is high and can thus be a major problem. Later, in searching the database for information to generate alerts, quality assurance, severity scores, medical decision making, or research, the drawback of having data in various places and in different forms creates major difficulties.

These problems are compounded when one tries to transfer data between computers, such as in downloading to relational database programs for research purposes.[35-37] Communicating between different types of computers having a different operating system can become very difficult.[35-37] The hospital business computer designed and programmed to process financial data is typically difficult to interface with clinical computer systems. Such communication, however, can be most valuable for automatic billing, administrative work, and research on the cost of health-care delivery. The ability to transfer mainframe programs between institutions for collaborative research efforts is nearly impossible today because such systems' coding, terms, and definitions are different. The need for standardization in this area is great, and the speed with which that progress is made in medical informatics will depend on such standardization.[2,38,39]

CLINICAL USE OF THE INFORMATION SYSTEM

The proof of the success of a medical informatics department is its acceptance and use clinically for patient care. The goal should be more than just facilitating the availability of data in a timely fashion for the clinician. A well-designed system should improve patient care above and beyond that which would be possible with the manual system. There are certain tasks computers do better than clinicians, and the system should take advantage of this fact to enrich the quality of care.

Friendly, fast, and flexible

The time required for the physician and other health-care personnel to interact with the computer is critical. The system must be fast and reliable, have minimal delays, and be user-friendly. With little or no training, the user should be able to find the desired clinical information and generate reports. The menus must be logical and easy to follow, leading the novice to the right place in each "document." When possible, the system should be flexible so that users can create their own menus or reports to satisfy special needs. This must be controlled, however, for the good of the entire system. The importance of the interface and user-friendliness was clearly demonstrated by Apple Computer in its challenge to IBM.

The organization and display of the terminal screens and the design of output reports can be crucial to the care of the patient and to the acceptance of the system by the clinical team. With an

integrated database many options are available, and the data can be organized in different formats for various functions and purposes.[40] This collaboration with clinical-care providers is critical because they are the primary users. The reports can be used to integrate data and emphasize specific related areas.[41,42] Certain data can be "flagged" to focus attention on problems,[43] and interpretations can be generated to help those who may be unfamiliar with the meaning of the data.[3,5] Graphs, tables, and charts can be used to show trends or to correlate information. The design of the output screens and reports is a science and can clearly enhance the success and utilization of the system.[44,45] Because it is difficult for clinicians to retain so much data in their minds, the display of previous data with the current data is extremely useful. In our setting, use of this display type for all laboratory data and for physiologic parameters has become routine. It is also valuable to cluster associated data. An example of this feature is when active cardiovascular drugs are displayed with hemodynamic data so the clinician can see the level of support being given when he or she is interpreting the cardiac performance.[43] Problems arise with various types of displays, however. For example, with the use of graphics one may encounter problems with resolution as well as difficulty in interpolating the digital numbers from the display. Other problems include difficulty in handling multiple scales, overlap of data and time scales, and the use of color displays versus black and white. Color displays help to resolve some problems but significantly increase the cost of a hospital-wide system of possibly hundreds of terminals and printers. In addition, most users have their own biases. Some like the advantage of trend overview in graphs, while others want to see the digital data. Some feel graphs help to correlate data, and others find them too slow and a nuisance. Because the use of the data is so varied, obtaining consensus on the format of reports is impossible. Again, close communications between the medical informaticist and the user is indispensable in resolving these issues.

Data-driven automatic alerts and alarms

One area in which the clinician has difficulty is in handling the overload of data both from the patient and from the literature.[46] Thus when a parameter becomes available along with scores of other variables, it may be overlooked or fail to be properly integrated with other information from the patient's database or from the literature. The result is that a potentially dangerous situation may not be recognized. The computer is very good at processing every new piece of information and comparing it with other available data and with data in its internal knowledge base. Thus an important role of the information system is to feed back to healthcare providers alerts concerning potentially dangerous situations. This can be in the realm of drug-drug interactions or incompatibilities, drug-allergy situations, drug dosage and organ dysfunction, or critical changes in laboratory and physiologic parameters. Such alerting is best automated and data-driven. The integrated system that has simultaneous access to the patient's laboratory data; allergy, height, weight, and age information; and diagnosis on admission, medications, and physiologic parameters allows for much more sophisticated alerting programs to be created.[7-14,47,48]

A great deal of experience and skill is required to develop a system that is user-friendly, acceptable by the caregiver, and helpful without being annoying. The use of redundant information to avoid false alerts can be helpful.[7-14,49] The careful evaluation of alerts and their categorization into levels of urgency so as not to overburden the clinician with minor or postponable concerns makes the system more acceptable. At times the alerts may be channeled through pharmacists, nurses, or other paramedical professionals who can screen or respond to the alarm without alerting the physician.[47,50] In cases in which the system allows or demands the physician's personal entry of orders into the computer, immediate computer feedback at the time of ordering can be useful if done in a timely fashion, when the information is most important.

Stratifying the urgency of the alerts with different mechanisms appropriate to the urgency can be used for feedback. For example, a life-threatening alert should be more urgent than an "information only" alert. An annoying sound or light that can only be turned off by recognizing the alert is the most effective way to guarantee attention but is not appropriate for most alerts that do not require immediate attention. If nurses carry floor pagers, the computer can send a message through the paging system to notify them of an alert. A less annoying method of presenting the alerts to the care provider is to bring up an alert screen each time one looks at the patient's database file or enters a patient order. This method is not as sure or as timely but may be adequate for many messages. At other times a report printed once a day may suffice.

Ensuring quality care

The value of a well-designed alerting system is clear.[48] It allows the care provider to avoid potential dangers before the institution of therapy and to avoid incompatible orders. Alerts and prompts also can be used to reduce costs by reminding physi-

cians of more cost-effective medications or procedures that would adequately satisfy the situation.[14,15,32,51,52] Uses of the alerting system for online quality control are many. For example, when one is ordering total parenteral nutrition (TPN) solutions, the program can alert the physician of incompatibilities and disallow specific combinations of calcium and phosphates, depending on pH.[53] The program can also prevent the addition of medications known to be unstable in the solution. In an order for antibiotics, the dosage can be questioned as to its appropriateness for renal or liver function or for the size/weight of the patient. An order for intravenous potassium can be questioned or denied if dangerous infusion rates are exceeded. When drugs that interact with others are ordered, the physician can be reminded of potential problems. Such alerting systems have proved to be highly effective, with a physician compliance to computer suggestions at greater than 90%.[25,30,49] These systems have also been shown to improve the use of blood products and allow the measurement of improvement in transfusion practice.[32,51,52]

These same principles can be carried over to cost-containment efforts by giving physicians suggestions to use less costly antibiotics appropriate for the given diagnosis and bacteriology results.[10,11] Reminders to stop medications have also proved to be highly effective at reducing costs and improving the quality of care, especially in the area of perioperative prophylactic antibiotics.[14,15,82] Timely feedback to physicians of potentially dangerous situations such as metabolic acidosis, when coupled with suggestions on how to proceed with patient evaluation and therapy, has been demonstrated to both reduce the time the patient remains acidemic and improve outcome.[4]

Similar to the alerting system, real-time quality assurance reports can be used to improve the quality and cost of care. Most hospitals in the United States do quality assurance by defining criteria for quality and then through a random chart review determine the compliance with this predetermined level of care. Then with the aid of educational or procedural mechanisms, hospitals attempt to improve the quality. Subsequently they restudy the problem by a second random chart review to determine the success of the instituted measures. With a computerized database, criteria designated for quality care can be explicitly described, and when breeches in that standard are found through uninterrupted computer surveillance, an immediate report can be generated to the quality assurance personnel so that the situation can be corrected immediately.[54] This allows real-time improvement in care, along with the institution of educational and procedural steps. This monitoring can be continued indefinitely and applied to every patient, not just those randomly chosen for review. Thus quality assurance can be vastly improved over manual, retrospective chart review.

Computer monitoring can also dramatically improve identification of problems. For example, when adverse drug reactions are detected by a continuous computer surveillance program, the rate of detecting adverse reactions was 60 times higher than when reported by hand.[12,55] These types of audits are only achievable with an integrated clinical decision-making data system.

The best measures of quality care are outcome and cost. Because of the inhomogeneity of patients, disease expression, and care processes, however, the ability to define and determine quality of care by using outcome and cost is very difficult. To help avoid these problems, acuity scoring systems—the Acute Physiologic and Chronic Health Evaluation (APACHE),[29,56,57] the Computerized Severity Index (CSI),[84] the Therapeutic Intervention Scoring System (TISS),[57,58] the Injury Severity Score (ISS),[59,60] and others[61]—have been created with statistical methods linked to diagnosis to allow outcome prediction and to measure to some degree the quality of care. Scoring every patient in longhand is laborious, time-consuming, and costly. With some effort directed toward computerization, these scores can be calculated automatically and stored as a part of the medical record. Then statistical methods can be used to continually assess the quality of care.

Another technique used to improve quality of care is to gather data prospectively from a specific group of patients for administrative, quality assurance, and research purposes.[41,42] These patients can be automatically identified by computer screening and their records placed into specific data sets such as trauma, respiratory failure, or cancer registries. Furthermore, this standardized, prospectively gathered database can then be analyzed for various purposes to provide bases for legislation, funding, research, and quality control.

The design and use of reports and summaries derived from the database can be most useful in quality control. Timely data on infectious complications, resource utilization, procedures performed, patient demographics, staffing patterns, and outcomes can be highly valuable in identifying problems. Once problems are identified, administrative steps can be taken to plan for improved quality of patient care.[17,62] In this, it is important to maximize the cost-to-benefit ratio. But when cost-reduction measures are implemented, the assessment of the impact on care is critical to ensure that

outcome is not compromised. Again, real-time reports generated from the database can be valuable in optimizing and managing this process.

Standardization of care

There are many advantages to standardizing care, and the computer lends itself nicely to this task. In hospitals that care for a large volume of a certain type of patient, such as those having coronary artery bypass surgery, outcome improves.[63] Much of this improvement is due to the routine or standardization of care that results from repetitive care. Whenever care is delivered in a standardized fashion, mistakes are reduced. For example, ICUs require the mixing of intravenous infusion drugs. Administration of incorrect doses is more common when drugs are mixed differently each time than when the concentration is always the same. In addition, the care is more uniform if all care team members use the same principles and decision logic each day and on every shift.[64-65] Communications are enhanced as well when everyone uses the same terminology and interprets the data similarly.

Standardization can reduce cost by reducing the inventory of supplies and drugs required by the institution. Routine also reduces waste and personnel time. With standardization, quality assurance programs are strengthened because it is easier to identify breeches in the standards. In institutions that commonly accept standardization, changes that improve care are simplified and more readily accepted.

One of the major problems today is the difficulty in defining how we care for patients. For example, the process of care of a ventilator-dependent patient varies considerably, depending on both the hospital or ICU and the varying style of different attending physicians. In this case it is thus difficult to know if one method of ventilator care is better than another and how to modify the process of care to improve outcome. Standardization of care facilitates the identification of areas in which improvement can be made and allows evaluation of the effectiveness of changes in the standard.[66-72]

One method to bring standardization into the care environment is to use the computer to guide physicians' orders. This is effective in the ordering of more complex items such as TPN.[53] With the knowledge of the patient's sex, age, height, and weight, along with the use of the Harris-Benedict equations, one can calculate a computer-estimate of caloric needs along with a standard mixture of proteins, lipids, and carbohydrates. In addition, factors such as the diagnosis, stress, and organ function can be factored in as determined by the nutritional experts who designed the program. The physician is given the option of modifying the solution but begins at a starting point that is standardized for the patient's needs. This saves the physician time and effort and reduces errors made by physicians inexperienced in ordering TPN. Electrolyte concentrations are then suggested, based on the patient's latest serum values. The physician can select the suggested package or modify it. If the physician selects incompatible or dangerous concentrations, alerts are presented on the screen. Then standard nursing procedures and monitoring, such as daily intake and output, weights, and 6-hour urine glucose checks, are automatically ordered. The computer thus allows subtle control of how care is delivered to be maintained through indirect expert guidance or critiquing. The number of calories, as well as composition of nutrients, electrolytes, and nursing care related to the TPN, are thereby controlled to some degree and the inventory of products reduced.[53] Similar programs for antibiotic ordering[14,15] and blood banking[51,52] have also been developed.

Computer-assisted orders also can improve quality assurance measures, as specific information, such as the indication for transfusion, can be recorded for audit purposes and[51] order overrides reviewed later for appropriateness. Complications can be reviewed to check logic errors and deficiencies in the computer guidance. Thus standardization facilitates identification of problems and allows potential solutions to be proposed and validated.

The computer-guided TPN orders are flexible enough to allow the individual physician to maintain control and feel "in charge." If designed properly, these and similar orders can assist physicians and make their task easier, thus enticing compliance. A more severe type of control can be imposed for specific purposes but requires a good deal of coordination and cooperation to introduce. For research purposes, detailed protocols that maintain tight control of the process of care have been developed.[31,66-72] Experience with and acceptance of such control is limited and is often resisted by the members of medical staffs who have been schooled in making decisions tailored to the needs of the individual patient and clinical situation and who thus believe such control to be detrimental to good care. The proof of such logic is lacking, however, and many authors are challenging it by demonstrating the inconsistencies in medical practice and decision making.[64] These authors also point out that because of this ideation physicians are unsure of the benefit of much of the care they now deliver.[65] The use of rigid computerized protocols permits control of the process of medical care in such a way that will provide answers to many questions involved in that process—answers that, until now, have been difficult to establish.[82]

RESEARCH USES OF THE INFORMATION SYSTEM

If the initial obstacles to entering quality data into the information system and proper coding and storage are overcome, the system becomes a powerful research tool to provide useful data that can be accessed by investigators. The next hurdle for the clinical investigator is to develop mechanisms whereby the data in the integrated system can be put into a format for review and statistical analysis. This can be accomplished in several ways, but perhaps the most satisfactory is to have the capability to download the desired information easily into a research computer database. The original decisions concerning coding and storage of data become vital to the process at this point. When research use of the information is contemplated, establishing a coding system is crucial in the system's design.

When the clinical trial cannot be blinded, such as in the use of extracorporeal support for respiratory failure, bias becomes a major issue. Bias can be significantly reduced by using computerized protocols to deliver care in both arms of the study,[82] thus removing bias from that aspect of care by front-end agreement on how care will be delivered.

When designing clinical research projects, one objective is to reduce "noise" as much as possible. One method of accomplishing this task is to develop tight control of the process of care, which can enable us to obtain a credible answer with a significance not previously attainable.[66,70-72] For example, we have used this methodology to determine if a new method of caring for a ventilator patient is superior to another. To answer such a question, both methods of care must be defined and carried out in a randomized fashion. The control over the process of care conveys with it the following advantages: (1) reducing both random and nonrandom bias in the experiment, (2) permitting the investigators to describe precisely their methods of care, and (3) allowing others to challenge the results by duplicating the methods later.[30,82] However, the cooperation of all physicians, nurses, and therapists involved, and a commitment to abandoning stylistic differences to override the protocols (only for valid identifiable reasons), is required.[66,72]

Our experience with development and use of computerized protocols is that outcome is improved.[67,71,82] As the standardization process becomes mature, clinical personnel find it easier to care for the patients and want to use the protocols for clinical care outside the research study.[66,70] Computerized protocols also provide a tool to answer other questions that may arise about ventilator care. We have found that the computer database is not only a powerful tool in running complex protocols but also reduces the errors commonly made when following protocols of paper flow diagrams.[25] Whether it is the protocols per se or the process of developing the standardization of ventilator care that improve outcome is not clear and requires further research.

Another unique advantage of a universal database is that all nurses' and therapists' tasks, along with supplies, laboratory, x-ray examinations, and clinical procedures, are recorded in the database. From time-motion studies of each of these tasks, personnel time is measured. Thus the true costs of each task and procedure can be determined. It then becomes possible to calculate from the database the true cost of caring for patients.[73-76] This allows research in the area of cost, charges, and reimbursement to be carried out easily and with greater accuracy than was previously possible, thus adding a valuable dimension to clinical outcomes research efforts.

LOGISTICS OF RUNNING AN INTEGRATED SYSTEM

Hardware/software failures and downtime

Nowhere in medicine is there greater need for timely and accurate data than in the ICU. Patients' physiologic parameters are changing beat by beat and breath by breath. Fast system response time and continual availability are crucial goals that must be achieved before nurses, therapists, and physicians will trust and use computer systems. At LDS Hospital in Salt Lake City, the system is available 99.6% of the time. When it is not available (0.4%, or on average 5.77 minutes per day), about half the time it is for planned downtime for hardware and software maintenance and the other half is for unplanned failures. These unplanned failures might be a result of electrical storms, software glitches, and so forth. Every effort must be taken to minimize downtime. Redundant hardware, battery-powered backup power supplies, carefully tested and "debugged" software, systems disk backups, and a host of other steps must be taken to achieve such capabilities.[78] Systems with such reliability are now found in several places in our society, such as in banks with automatic tellers and in airline reservation and seat-scheduling systems. Imagine what it would be like at a busy airport in loading a 747 jet if there were no computers! The same will be true for the hospital and ICU system of the future.

Confidentiality of computerized patient records

Confidentiality of patient records is a "right" expected by the patient in the ICU. Public revelations of "confidential" data are seldom a problem but

could be in the future. Confidentiality of handwritten paper records is usually maintained by keeping the record "in the unit." Unfortunately, the same factors that limit the usefulness of the conventional paper record also give some measure of security to it. The computerized record can be made secure and confidential to a point at which it may not be useful to anyone caring for the patient. Therefore, a balance between confidentiality and reasonable access must be achieved. Current procedures to allow reasonable access to patient records include the following. (1) All employees and physicians are given "log on" codes and are required to use them before they can review patient data. These keys expire at frequent intervals (6 months is typical). (2) Hospital employees, typically admitting clerks, who need only access a limited data set do not have access to all patient data. Only select management physicians and computer personnel have system-wide access. (3) Every access to clinical information is logged. (4) Terminals left unattended log off after 5 minutes. (5) If a very important person (VIP) is admitted, access to any of his or her data is preceded by a special caution message. (6) Procedures are in place to handle breaches in security.

How to achieve an integrated medical informatics system

As the recent Institute of Medicine Report (IOM) states, "The patient record touches, in some way, virtually everyone associated with providing, receiving, or reimbursing health care services."[2] With computer technology ubiquitous in our society, there is the temptation to "hook up a PC" to do the task. Unfortunately, such simple approaches to building simple "stand-alone" systems that do not interface with other systems and that do not use a structured and integrated approach are doomed to failure. Data integration and communications are the keys to providing the health-care professional with something currently impossible with manual charting methods. There must be minimal changes in the user's environment as computers are introduced. Consistency in how data are acquired, in how the parameters are recorded, in the frequency of recording, and in who records the data is crucially important. Many of the issues are not technological, but are "sociological."[78] A team spirit must exist so that the complex interactions that have been worked out over decades with manual methods can be implemented with computers. Cost of implementation must take into consideration not only the hardware and software costs, but the "people-ware" costs of training users, educating users as to the system benefits, and evaluating those benefits.

The expectations of society for medical progress and increased use of computers for diagnosis and treatment are fueled by the increased use of computers in everyday life and in science fiction movies, and by the eternal optimism that drives the curiosity about the future. At the same time great strides have been made in understanding how to harness computer technology to help the health-care professional in the care of the critically ill patient.[79]

Again, it seems clear that advances in the use of computers in the hospital and in the ICU will be evolutionary rather than revolutionary. Part of the health-care system will require modification before optimally integrated systems will be widespread. The method with which health-care professionals interact with their patients and colleagues will change. Intensive care medicine is clearly ready for the new challenges of the future.[80]

REFERENCES

1. Leyerle BJ, LoBue M, Shabot MM: The PDMS as a focal point for distributed patient data, *Int J Clin Monit Comput* 5:155-161, 1988.
2. Dick RS, Steen EB, editors: The computer-based patient record: an essential technology for health care. Washington, DC, 1991, Institute of Medicine, National Academy of Sciences Press.
3. Gardner RM, Cannon GA, Morris AH, et al: Computerized blood gas interpretation, *Med Instrum* 8:126, 1974.
4. Johnson DS, Ranzenberger J, Herbert R, et al: A computerized alert program for acutely ill patients, *J Nurs Adm* 10(6):26-35, 1980.
5. Clemmer TP, Gardner RM, Orme JF Jr: Computer support in critical care medicine, *SCAMC* 4:1557-1561, 1980.
6. Gardner RM: Computerized management of intensive care patients, *MD Comput* 3:36-51, 1986.
7. Bradshaw KE, Gardner RM, Pryor TA: Development of a computerized laboratory alerting system, *Comput Biomed Res* 22:575-587, 1989.
8. Tate KE, Gardner RM, Weaver LK: A computerized laboratory alerting system, *MD Comput* 7(5):296-301, 1990.
9. Kuperman GJ, Gardner RM, Pryor TA: *HELP: a dynamic hospital information system,* New York, 1991, Springer-Verlag.
10. Pestotnik SL, Evans RS, Burke JP, et al: Therapeutic antibiotic monitoring: surveillance using a computerized expert system, *Am J Med* 88:43-48, 1990.
11. Evans RS: The HELP system: a review of clinical applications in infectious disease and antibiotic use, *MD Comput* 8:282-288, 1991.
12. Classen DC, Pestotnik SL, Evans RS, et al: Computerized surveillance of adverse drug events in hospital patients, *JAMA* 266:2847-2851, 1991.
13. Evans RS, Gardner RM, Bush AR, et al: Development of a computerized infectious disease monitor (CIDM), *Comput Biomed Res* 18:103-113, 1985.
14. Larsen RA, Evans RS, Burke JP, et al: Improved perioperative antibiotic use and reduced surgical wound infections through use of computer decision analysis, *Infect Control Hosp Epidemiol* 10:316-320, 1989.
15. Evans RS, Pestotnik SL, Burke JP, et al: Reducing the duration of prophylactic antibiotics use through computer monitoring of surgical patients. DICP, *Ann Pharmacother* 24:351-354, 1990.

16. Shabot MM, LoBue M, Leyerle BJ, et al: Decision support alerts for clinical laboratory and blood gas data, *Int J Clin Monit Comput* 7:27-31, 1990.
17. Bradshaw KE, Sittig DF, Gardner RM, et al: Computer-based data entry for nurses in the ICU, *MD Comput* 6(5):274-280, 1989.
18. Gardner RM, Tariq H, Hawley WL, et al: Medical information bus: the key to future integrated monitoring, *Int J Clin Monit Comput* 6:205-209, 1989 (editorial).
19. Gardner RM, Hawley WH, East TD, et al: Real time data acquisition: experience with the Medical Information Bus (MIB), *SCAMC* 15:813-817, 1991.
20. Gardner RM, Hawley WH, East TD, et al: Real time data acquisition: recommendations for the Medical Information Bus (MIB), *Int J Clin Monit Comput* 8:251-258, 1992.
21. East TD, Yang W, Tariq H, et al: The IEEE medical information bus of respiratory care, *Crit Care Med* 17:580, 1989.
22. Shabot MM: Standardized acquisition of bedside data: the IEEE P1073 medical information bus, *Int J Clin Monit Comput* 6:197-204, 1989.
23. Gardner RM, Clemmer TP, Morris AH: Computerized medical decision making—an evaluation in acute care. Proceedings of Computers in Critical Care and Pulmonary Medicine, Lund, Sweden, June 1980.
24. Toong HD, Gupta A: Personal computers, *Sci Am* 247(12):87-105, 1982.
25. Henderson S, Crapo RO, East TD, et al: Computerized clinical protocols in an intensive care unit: how well are they followed?, *SCAMC* 14:284-288, 1990.
26. Brahams D, Wyatt J: Medicine and the law, *Lancet* Sept 1989, pp 632-634.
27. Gravenstein JS, DeVries A Jr, Beneken JFW: Sampling intervals of clinical monitoring variables during anesthesia, *J Clin Monit* 5:17-21, 1989.
28. Bradshaw KE, Gardner RM, Clemmer TP, et al: Physician decision-making—evaluation of data used in a computerized ICU, *Int J Clin Monit Comput* 1:81-91, 1984.
29. Knaus WA, Wagner DP, Lynn J: Short-term mortality predictions for critically ill hospitalized adults: science and ethics, *Science* 254:389-394, 1991.
30. Sittig DF, Gardner RM, Morris AH, et al: Clinical evaluation of computer-based respiratory care algorithms, *Int J Clin Monit Comput* 7:177-185, 1990.
31. Sittig DF, Gardner RM, Pace NL, et al: Computerized management of patient care in a complex, controlled clinical trial in the intensive care unit, *Comput Meth Prog Biomed* 30:77-84, 1989.
32. Gardner RM, Laub RM, Golubjatnikov OK, et al: Computer critiqued blood ordering using the HELP system, *Comput Biomed Res* 23:514-528, 1990.
33. Pryor TA, Gardner RM, Clayton PD, et al: The HELP system, *J Med Syst* 7:87-102, 1983.
34. Pryor TA: The HELP medical record system, *MD Comput* 5:22-33, 1988.
35. McDonald CJ: The search for national standards for medical data exchange, *MD Comput* 1:3-4, 1984.
36. McDonald CJ: Interchange standards revisited, *MD Comput* 7:72-74, 1990.
37. McDonald CJ: Hammond WE: Standard formats for electronic transfer of clinical data, *Ann Intern Med* 110:333-335, 1989 (editorial).
38. Report to Congress: The feasibility of linking research-related data bases to federal and non-federal medical administrative data bases, AHCPR Pub No 91-003, Washington, DC, April 1991, Agency for Health Care Policy and Research.
39. Report to Congress: Progress of research on outcomes of health care services and procedures, AHCPR Pub No 91-004, Washington, DC, May 1991, Agency for Health Care Policy and Research.
40. Gardner RM, Scoville DP, West BJ, et al: Integrated computer systems for monitoring of the critically ill, *SCAMC* 1:301-307, 1977.
41. Sittig DF, Gardner RM, Elliott CG: Screening for adult respiratory distress syndrome patients: use of the HELP hospital information system, *J Clin Eng* 14:237-243, 1989.
42. Evans RS, Burke JP, Classen DC, et al: Computerized identification of patients at high risk for hospital-acquired infections, *Am J Infect Control* 20:4-10, 1992.
43. Gardner RM, Clemmer TP: Computerized protocols applied to emergency and acute care, *J Emerg Med Serv* 7(6):90-93, 1978.
44. Helander M, editor, *Handbook of human-computer interaction,* ed 2, New York, 1991, North-Holland.
45. Cole WG: Quick and accurate monitoring via metaphor graphics, *SCAMC* 425-429, 1990.
46. McDonald CJ: Protocol-based computer reminders, the quality of care and the non-perfectibility of man, *N Engl J Med* 295:1351-1355, 1976.
47. Hulse RK, Clark SJ, Jackson JC, et al: Computerized medication monitoring system, *Am J Hosp Pharm* 33:1061-1064, 1976.
48. Gardner RM, Clemmer TP, Larsen KG, et al: Computerized alert system use in clinical medicine. *Proc. 32nd Annual Conference of Engineering in Medicine and Biology,* Denver, 1979, p 1-5.
49. Gardner RM, Hulse RK, Larsen KG: Assessing the effectiveness of a computerized pharmacy system, *SCAMC* 14:668-672, 1990.
50. Miller PL: Goal-directed critiquing by computer: ventilator management, *Comput Biomed Res* 18:422-438, 1985.
51. Lepage ER, Gardner RM, Laub RM, et al: Assessing the effectiveness of a computerized blood order "consultant" system, *SCAMC* 15:33-37, 1991.
52. Lepage EF, Gardner RM, Laub RM, et al: Improving blood transfusion practice: role of a computerized hospital information system, *Transfusion* 32:253-256, 1992.
53. Larsen KG, Clemmer TP, Nicholson L, et al: Computer support in monitoring of nutritional therapy, *Nutr Support Serv* 3(6):7-16, 1983.
54. Elliott CG: Computer-assisted quality assurance: development and performance of a respiratory care program, *Qual Rev Bull* 17:85-89, 1991.
55. Evans RS, Pestotnik SL, Classen DC, et al: Development of a computerized adverse drug event monitor, *SCAMC* 15:23-27, 1991.
56. Knaus WA, Draper EA, Wagner DP, et al: DJ, Evaluating outcome from intensive care in major medical centers, *Ann Intern Med* 104:408-410, 1986.
57. Shabot MM, Leyerle BJ, LoBue M: Automatic extraction of intensity-intervention scores from a computerized surgical intensive care unit flowsheet, *Am J Surg* 154:72-78, 1987.
58. Cullen DJ, Civetta JM, Briggs BA, et al: Therapeutic intervention scoring system: a method for quantitative comparison of patient care, *Crit Care Med* 2:57, 1974.
59. MacKenzie EJ, Steinwachs DM, Shankar BS, et al: An ICD-9-CM to AIS conversion table: development and application, *Proc. 30th Annual Meeting of the American Association for Automotive Medicine,* Montreal, October 1986.
60. Baker SP, O'Neill B, Hadden W Jr, et al: The Injury Severity Score: a method for describing patients with multiple injuries and evaluating emergency care, *J Trauma* 14:187-196, 1974.
61. Horn SD, Sharkey PD, Buckle JM, et al: The relationship between severity of illness and hospital length of stay and mortality, *Med Care* 305-317, 1991.
62. Kuperman GJ, Maack BB, Bauer K, et al: Impact of the HELP system on the LDS hospital medical record, *Top Health Rec Manage* 12:76-85, 1991.

63. Berwick DM: The double edge of knowledge, *JAMA* 266:841-842, 1991.
64. Eddy DM: Clinical decision making from theory to practice: the challenge, *JAMA* 263:287-290, 1990.
65. Eddy DM: Clinical decision making from theory to practice: anatomy of a decision, *JAMA* 263:441-443, 1990.
66. East TD, Morris AH, Clemmer TP, et al: Development of computerized critical care patients—a strategy that really works!, *SCAMC* 14:564-568, 1990.
67. Morris AH, Wallace CJ, Clemmer TP, et al: Extracorporeal CO_2 removal therapy for adult respiratory distress syndrome patients: a computerized protocol controlled trial, *Reanimation Soins Intensifs Medecine d'Urgence* 6:485-490, 1990.
68. East TD, Bohm SH, Peng L, et al: A successful computerized protocol for clinical management of PC-IRV in ARDS patients, *Chest* 101:697-710, 1992.
69. East TD, Henderson S, Morris AH, et al: Implementation issues and challenges for computerized clinical protocols for management of mechanical ventilation in ARDS patients, *SCAMC* 13:583-587, 1989.
70. Henderson S, East TD, Morris AH, et al: Performance evaluation of computerized clinical protocols for management of arterial hypoxemia in ARDS patients, *SCAMC* 13:588-592, 1989.
71. Suchyta MR, Clemmer TP, Orme JF Jr, et al: Increased survival of ARDS patients with severe hypoxemia (ECMO criteria), *Chest* 99:951-955, 1991.
72. Henderson S, Crapo RO, Wallace CJ, et al: Performance of computerized protocols for management of arterial oxygenation in an intensive care unit, *Int J Clin Monit Comput* 8:271-280, 1992.
73. Thomas F, Larsen K, Clemmer TP, et al: Impact of prospective payment on a tertiary care center receiving large numbers of critically ill patients by aeromedical transport, *Crit Care Med* 14:227-230, 1986.
74. Thomas F, Fox J, Clemmer TP, et al: The financial impact of Medicare diagnosis-related groups: effect upon hospitals receiving cardiac patients referred for tertiary care, *Chest* 91(3):418-423, 1987.
75. Thomas F, Clemmer TP, Larsen KG, et al: The severity, outcome, cost of care, and economic impact under DRG payment policies of trauma patients referred to a major trauma center, *J Trauma* 28:446-452, 1988.
76. Clemmer TP, Orme JF Jr, Thomas FO, et al: The impact of Medicare prospective reimbursement system on nutritional support service patients: the importance of pass throughs, *JPEN* 13:71-76, 1989.
77. Gray J, Siewiorek DP: High-availability computer systems, *Computer* 24(9):39-48, 1991.
78. Lundsgaarde HP, Gardner RM, Menlove RL: Using attitudinal questionnaires to achieve benefits optimization, *SCAMC* 13:703-708, 1989.
79. Gardner RM, Shabot MM: Computerized ICU data management: pitfalls and promises, *Int J Clin Monit Comput* 7:99-105, 1990.
80. Rand T: Automated records aren't such a stretch, *Healthweek* 5(17):4-8, 1991.
81. Classen DC, Evans RS, Pestotnik SL, et al: The timing of prophylactic administration of antibiotics and the risk of surgical-wound infection, *N Engl J Med* 326:281-286, 1992.
82. Morris AH, Wallace CJ, Menlove RL, et al: Randomized clinical trial of pressure-controlled inverse ratio ventilation and extracorporeal CO_2 removal for adult respiratory distress syndrome, *Am J Respir Crit Care Med* 149:295-305, 1994.
83. Oniki TA: Computerized detection of arterial oxygen desaturation in an intensive care unit, *SCAMC* 17:356-360, 1993.
84. Horn SD, Horn RA: The Computerized Severity Index: a tool for case mix management, *J Med Syst* 10:73-78, 1986.